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Our Docket No. CMCC 654 DIV (2) **Client/Matter No.** 078856-00059

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MESSAGE:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant: Bruce A. Yankner and Philip Nadeau

Serial No.: 10/086,398 **Art Unit:** 1617

Filed: February 28, 2002 **Examiner:** Theodore J. Criares

For: *METHODS FOR DECREASING BETA AMYLOID PROTEIN*

PTO/58/17 (10-03)

Approved for use through 07/31/2006, OMB 0651-0032
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FEE TRANSMITTAL
for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27**TOTAL AMOUNT OF PAYMENT** (\$ 330**Complete if Known**

Application Number	10/086,398
Filing Date	February 28, 2002
First Named Inventor	Bruce A. Yankner
Examiner Name	Theodore J. Crlares
Art Unit	1617
Attorney Docket No.	CMCC 654 DIV (2)

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Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	60	Provisional filing fee	
SUBTOTAL (1)					(\$ 0)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims		Extra Claims		Fee from below	Fee Paid
Independent Claims	Multiple Dependent	20+	3-19		
7	1	20+	3-19	0	0

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1202	18	2202	9	Claims in excess of 20	
1201	86	2201	43	Independent claims in excess of 3	
1203	280	2203	145	Multiple dependent claim, if not paid	
1204	88	2204	43	** Reissue independent claims over original patent	
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent	
SUBTOTAL (2)					(\$ 0.00)

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FEE CALCULATION (continued)**3. ADDITIONAL FEES**

Large Entity Small Entity

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1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for ex parte reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	330
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	840	2503	320	Plant issue fee	
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1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	160	1806	160	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
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SUBTOTAL (3) (\$ 330**SUBMITTED BY**

Name (Print/Type)	Rivka D. Monheit	Registration No. (Attorney/Agent)	48,731	Telephone	(404) 879-2152
Signature	<i>Rivka D. Monheit</i>	Date	September 23, 2004		

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PTO/SB/21 (08-03)

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TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/086,398	
	Filing Date	February 28, 2002	
	First Named Inventor	Bruce A. Yankner	
	Art Unit	1617	
	Examiner Name	Theodore J. Criares	
Total Number of Pages in This Submission	14	Attorney Docket Number	CMCC 654 DIV (2)

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Firm or Individual name	Rivka D. Monheit, Esq., Reg. No. 48,731 Pabst Patent Group LLP 400 Colony Square, Suite 1200, Atlanta, GA 30361	
Signature	<i>Rivka D. Monheit</i>	
Date	September 23, 2004	

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CMCC 654 DIV (2) / 078856-00059

SEP 23 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant: Bruce A. Yankner and Philip Nadeau

Serial No.: 10/086,398

Art Unit: 1617

Filed: February 28, 2002

Examiner: Theodore J. Criares

For: *METHODS FOR DECREASING BETA AMYLOID PROTEIN*

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

This is an appeal from the final rejection of claims 23-29 in the Office Action mailed February 24, 2004, in the above-identified patent application. A Notice of Appeal was filed on July 23, 2004. The Commissioner is hereby authorized to charge \$330.00, the fee for the filing of this Appeal Brief for a large entity, to Deposit Account No. 50-3129. It is believed that no additional fee is required with this submission. However, should an additional fee be required, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 50-3129.

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CMCC 654 DIV(2)
078856.00059

U.S.S.N. 10/086,398
Filed: February 28, 2002
APPEAL BRIEF

(1) REAL PARTY IN INTEREST

The real parties in interest of this application are the assignee Children's Medical Center Corporation, Boston, MA, and the licensee Andrx Corporation, Davie, FL.

(2) RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to appellant, the undersigned, or appellant's assignee which directly affects, which would be directly affected by, or which would have a bearing on the Board's decision in this appeal.

(3) STATUS OF CLAIMS ON APPEAL

Claims 23-29 are pending and on appeal. Claims 1-22 have been cancelled.

(4) STATUS OF AMENDMENTS

The claims were last amended in the amendment submitted via facsimile on September 11, 2003. An appendix sets forth the claims on appeal.

(5) SUMMARY OF THE INVENTION

The claimed invention is a composition for decreasing the production of A β comprising an effective amount of a compound decreasing blood cholesterol levels to decrease A β production by neuronal cells in an individual at risk of developing Alzheimers. (page 2, summary of the invention). Suitable cholesterol lowering compounds include HMG CoA reductase inhibitors such as the statins (page 6, lines 13-15); compounds which decrease uptake of dietary cholesterol such as bile acid binding resins and fibrates (page 6, lines 19-21); inhibitors of cholesterol biosynthetic enzymes (page 6, lines 16-18); and other cholesterol lowering compounds such as probucol, nicotinic acid, garlic and garlic derivatives and psyllium

U.S.S.N. 10/086,398
Filed: February 28, 2002
APPEAL BRIEF

(page 6, lines 21-23). Treatment is based on administration of one or more compositions effective to lower cholesterol blood levels at least 10%, which is believed to be sufficient to decrease production of A β . (page 3, summary of the invention).

(6) ISSUES ON APPEAL

The issues presented on appeal are:

(i) whether claims 23-29 are novel as required by 35 U.S.C. § 102(a) over U.S. Patent No. 4,866,090 to Hoffman *et al.* ("Hoffman"); U.S. Patent No. 5,350,758 to Wannamaker *et al.* ("Wannamaker"); and U.S. Patent No. 5,362,732 to Spielvogel *et al.* ("Spielvogel").

(ii) whether claims 26 and 27 are non-obvious as required by 35 U.S.C. § 103(a) over U.S. Patent No. 5,350,758 to Wannamaker *et al.* ("Wannamaker").

(7) ARGUMENTS

(a) The Claimed Invention

Appellants have demonstrated that elevated levels of cholesterol are correlated with elevated A β levels in the brain. Example 1 demonstrates that cholesterol actually increases the level of A β in human neuronal cultures. Example 2 shows that dietary cholesterol increases A β levels in the brain. Example 3 shows that HMG CoA reductase inhibitors inhibit the production of A β by human neurons. These results demonstrate that human neurons treated with either lovastatin, simvastatin, compactin, fluvastatin or pravastatin have significantly decreased levels of A β relative to controls. Subsequent studies with humans have confirmed the association between elevated cholesterol levels and A β levels in the brain

U.S.S.N. 10/086,398
Filed: February 28, 2002
APPEAL BRIEF

In the preferred embodiment, individuals with these risk factors are treated to lower blood cholesterol levels prior to developing any mental impairment attributable to AD, based on accepted neuropsychiatric and diagnostic criteria in clinical practice. Treatment is based on administration of one or more compositions effective to lower cholesterol blood levels at least 10%, which is believed to be sufficient to decrease production of A β .

The claimed invention is very specific: a composition for decreasing the production of A β comprising an effective amount of a compound decreasing blood cholesterol levels to decrease A β production by neuronal cells in an individual at risk of developing Alzheimers. The amount required to achieve this benefit is less than the amount required to lower cholesterol in patients with elevated cholesterol. This is advantageous because the amount of active is less, decreasing cost and side effects, which are not insignificant with these drugs. More relevantly, it also distinguishes the prior art compositions, which are provided in amounts required to treat atherosclerosis.

(i) **Rejections Under 35 U.S.C. § 102**

The Legal Standard

For a rejection of claims to be properly founded under 35 U.S.C. §102, it must be established that a prior art reference discloses each and every element of the claims. *Hybritech Inc v Monoclonal Antibodies Inc*, 231 U.S.P.Q. 81 (Fed. Cir. 1986), *cert. denied*, 480 US 947 (1987); *Scripps Clinic & Research Found v Genentech Inc*, 18 U.S.P.Q.2d 1001 (Fed. Cir. 1991). The Federal Circuit held in *Scripps*, 18 U.S.P.Q.2d at 1010:

U.S.S.N. 10/086,398
Filed: February 28, 2002
APPEAL BRIEF

Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. . . . *There must be no difference* between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. (Emphasis added)

A reference that fails to disclose even one limitation will not be found to anticipate, even if the missing limitation could be discoverable through further experimentation. As the Federal Circuit held in *Scriptps, Id.*:

[A] finding of anticipation requires that all aspects of the claimed invention were already described in a single reference: a finding that is not supportable if it is necessary to prove facts beyond those disclosed in the reference in order to meet the claim limitations. The role of extrinsic evidence is to educate the decision-maker to what the reference meant to persons of ordinary skill in the field of the invention, not to fill in the gaps in the reference.

For a prior art reference to anticipate a claim, it must enable a person skilled in the art to practice the invention. The Federal Circuit held that "a §102(b) reference must sufficiently describe the claimed invention to have placed the public in possession of it. . . . [E]ven if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling." *Paperless Accounting Inc v Bay Area Rapid Transit Sys.*, 231 U.S.P.Q. 649, 653 (Fed. Cir. 1986) (citations omitted).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference. *Verdegaal Bros. v. Union*

U.S.S.N. 10/086,398
Filed: February 28, 2002
APPEAL BRIEF

Oil of California, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). A 102 rejection over multiple references is proper when the extra references cited show that a characteristic not disclosed is inherent. To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991).

The Prior Art

Claims 23-29 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,866,090 to Hoffman *et al.* ("Hoffman"); U.S. Patent No. 5,350,758 to Wannamaker *et al.* ("Wannamaker"); and U.S. Patent No. 5,362,732 to Spielvogel *et al.* ("Spielvogel").

Hoffman discloses analogs of lovastatin and related analogs which are useful alone or in combination with bile acid sequestrants as antihypercholesterolemic agents "for the treatment of arteriosclerosis, hyperlipidemia, familial hypercholesterolemia and like diseases in humans".

Wannamaker discloses pharmaceutical compositions which are inhibitors of cholesterol biosynthesis and are useful in lowering serum cholesterol levels in patients having chronically and significantly elevated cholesterol levels, particularly for treatment of atherosclerosis (background of the invention).

Spielvogel discloses a class of boronated compounds that have many different properties (anti-cancer, anti-inflammatory, analgesic, antiinfective) and which might also include activity in

U.S.S.N. 10/086,398
Filed: February 28, 2002
APPEAL BRIEF

lowering cholesterol. This is a hypothetical disclosure that provides such a broad range that it encompasses everything and enables nothing.

The Claimed Invention

The claims on appeal define a composition comprising an effective amount of a compound decreasing blood cholesterol levels to decrease A β production by neuronal cells in an individual at risk of developing Alzheimers. There is no teaching or suggestion in the prior art that the compounds disclosed have any effect on the production of A β protein in neuronal cells. The prior art fails to define this end point or what an effective dosage would be to achieve this endpoint.

Moreover, the dosages that are effective in lowering the amount of amyloid precursor protein to decrease production of A β are different from those versus lowering cholesterol to treat or prevent atherosclerosis are different. The appellants disclose that a 10% decrease in serum cholesterol levels is believed to be sufficient to decrease production of A β protein in neurons (page 3, lines 11-13). Such a decrease would not be clinically effective in treating hypercholesterolemia (see, for example, Spielvogel, Example 15).

(ii) **Rejections Under 35 U.S.C. § 103**

The Legal Standard

The U.S. Patent and Trademark Office has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. *In re Warner et al.*, 379 F.2d 1011, 154 U.S.P.Q. 173, 177 (C.C.P.A. 1967), *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598-99 (Fed. Cir. 1988). In rejecting a claim under 35 U.S.C. § 103, the Examiner must establish a *prima facie* case that:

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7

CMCC 654 DIV(2)
078856.00059

U.S.S.N. 10/086,398
Filed: February 28, 2002
APPEAL BRIEF

(i) the prior art suggests the claimed invention; and (ii) the prior art indicates that the invention would have a reasonable likelihood of success. *In re Dow Chemical Company*, 837 F.2d 469, 5 U.S.P.Q.2d 1529 (Fed. Cir. 1988).

The prior art must provide one of ordinary skill in the art with the motivation to make the proposed modifications needed to arrive at the claimed invention. *In re Gelger*, 815 F.2d 686, 2 U.S.P.Q.2d 1276 (Fed. Cir. 1987); *In re Lalu and Foulletier*, 747 F.2d 703, 705, 223 U.S.P.Q. 1257, 1258 (Fed. Cir. 1984). Claims for an invention are not *prima facie* obvious if the primary references do not suggest all elements of the claimed invention and the prior art does not suggest the modifications that would bring the primary references into conformity with the application claims. *In re Fritch*, 23 U.S.P.Q.2d, 1780 (Fed. Cir. 1992). *In re Laskowski*, 871 F.2d 115 (Fed. Cir. 1989). The Court of Appeals for the Federal Circuit warned that “the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for showing of the teaching or motivation to combine prior art references.” *In re Dembiczak*, 175 F.3d 994 at 999 (Fed. Cir. 1999). The “question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination. *WMS Gaming, Inc. v International Game Technology*, 184 F.3d 1339 at 1355 (Fed. Cir. 1999). “[T]he showing must be clear and particular.” *In re Dembiczak*, 175 F.3d 994 at 999 (Fed. Cir. 1999). Although with the answer in hand, the “solution” now appears obvious, that is not the test. The references must themselves lead those in the art to what is claimed. The references here do not disclose the disorder to be treated, the

U.S.S.N. 10/086,398
Filed: February 28, 2002
APPEAL BRIEF

selection of the composition to be used, nor the amount of active agent required. The composition therefore cannot be obvious.

The Prior Art

Claims 26 and 27 were rejected as obvious under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,350,758 to Wannamaker *et al.* ("Wannamaker").

Claims 26 and 27 are dependent on claim 23 and are directed to compounds which inhibit uptake of dietary cholesterol and which block or decrease endogenous cholesterol production, respectively. Claim 23 is directed to a composition for decreasing the production of A β comprising an effective amount of a compound decreasing blood cholesterol levels to decrease A β production by neuronal cells in an individual at risk of developing Alzheimers.

Wannamaker describes pharmaceutical compositions which are useful as inhibitors of squalene epoxidase and/or oxidosqualene cyclase and as a result inhibit cholesterol biosynthesis (col. 1, lines 10-13). Wannamaker describes pharmaceutical compositions which are useful as inhibitors of squalene epoxidase and/or oxidosqualene cyclase and as a result inhibit cholesterol biosynthesis (col. 1, lines 10-13).

There is no teaching or suggestion that the compounds disclosed would have any effect on the production of A β in neuronal cells. Accordingly, one of ordinary skill in the art would not be motivated to make or use the compounds disclosed by Wannamaker in an effective amount to inhibit the production of A β protein in neuronal cells.

U.S.S.N. 10/086,398
Filed: February 28, 2002
APPEAL BRIEF


(8) SUMMARY AND CONCLUSION

The prior art does not suggest that lowering cholesterol would have any effect on A β production in neuronal cells. The dosages required to decrease production of A β protein is different from that required to treat atherosclerosis, even though the serum component, cholesterol, is the same. Since the dosage is different, the claims are novel.

The prior art does not disclose the use of cholesterol lowering agents to decrease production of A β protein and therefore does not lead one to the selections required for one of ordinary skill in the art to make and use the claimed composition.

For the foregoing reasons, Appellants submit that claims 23-29 are patentable.

Respectfully submitted,


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Reg. No. 31,284

Date: September 23, 2004

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U.S.S.N. 10/086,398
Filed: February 28, 2002
APPEAL BRIEF

Appendix: Claims On Appeal

23. (previously amended) A composition for decreasing the production of A β comprising an effective amount of a compound decreasing blood cholesterol levels to decrease A β production by neuronal cells in an individual at risk of developing Alzheimers.
24. (original) The composition of claim 23 comprising an HMG CoA reductase inhibitor.
25. (original) The composition of claim 24 wherein the inhibitor is selected from the group consisting of lovastatin, simvastatin, fluvastatin, pravastatin, atorvastatin, cerivastatin, and compactin.
26. (original) The composition of claim 23 comprising a compound which inhibits uptake of dietary cholesterol.
27. (original) The composition of claim 23 wherein the composition blocks or decreases endogenous cholesterol production.
28. (original) The composition of claim 27 wherein the composition comprises an inhibitor of the cholesterol biosynthetic enzymes selected from the group consisting of 2,3-oxidosqualene cyclase, squalene synthase, and 7-dehydrocholesterol reductase.
29. (original) The composition of claim 23 wherein the composition is selected from the group consisting of a fibrate, a bile acid binding resin, probucol, nicotinic acid, garlic or garlic derivative, and psyllium.

TABLE OF CONTENTS

- (1) REAL PARTY IN INTEREST**
- (2) RELATED APPEALS AND INTERFERENCES**
- (3) STATUS OF CLAIMS ON APPEAL**
- (4) STATUS OF AMENDMENTS**
- (5) SUMMARY OF THE INVENTION**
- (6) ISSUES ON APPEAL**
- (7) ARGUMENTS**
 - (i) Rejections Under 35 U.S.C. § 102**
 - (ii) Rejections Under 35 U.S.C. § 103**
- (8) SUMMARY AND CONCLUSION**

Appendix: Claims On Appeal

Table of Contents

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